

IN THE CLAIMS

Please cancel claims 215, 218, 224-225, 228, 230, 232-233, 253, 255-358, 362, 368, 371 and 377-394.

I. Amendments to Pending Claims

Please substitute pending claims 211-214, 217, 219, 221-223, 234-235, 240-242, 245-248, 251, 359, 361, 365-367, 373 and 375-376 with the corresponding amended claims, as shown below.

211. A method for treating erectile dysfunction in a male subject, comprising administering in combination:

a) a hydroalcoholic topical gel composition to selected skin of a male subject, wherein the composition comprises about 0.1% to about 10% (w/w) testosterone, about 0.1% to about 5% (w/w) of at least one penetration enhancer, and about 0.1% to about 5% (w/w) of at least one gelling agent, and

b) a pharmaceutical selected from the group consisting of: sildenafil, pentoxifylline, yohimbine, apomorphine, alprostadil, papaverine, IC-351 (tadalafil) and phentolamine, or a combination, salt, or enantiomer thereof, wherein the composition and pharmaceutical are administered in amounts sufficient to treat the erectile dysfunction.

212. The method of claim 211, wherein the pharmaceutical comprises sildenafil in an amount of about 25 mg to about 100 mg.

213. The method of claim 211, wherein the pharmaceutical comprises apomorphine in an amount of about 1 mg to about 5 mg.

214. The method of claim 211, wherein the pharmaceutical comprises IC-351 (tadalafil) in an amount of about 5 mg to about 30 mg.

217. The method of claim 211, wherein the composition comprises about 1.0% w/w of testosterone.

219. The method of claim 211, wherein the penetration enhancer is selected from the group consisting of: isostearic acid, octanoic acid, oleic acid, oleyl alcohol, lauryl alcohol, ethyl oleate, isopropyl myristate, butyl stearate, methyl laurate, diisopropyl adipate, glyceryl monolaurate, tetrahydrofurfuryl alcohol polyethylene glycol ether, polyethylene glycol, propylene glycol, 2-(2-ethoxyethoxy)ethanol, diethylene glycol monomethyl ether, alkylaryl ethers of polyethylene oxide, polyethylene oxide monomethyl ethers, polyethylene oxide dimethyl ethers, dimethyl sulfoxide, glycerol, ethyl acetate, acetoacetic ester, N-alkylpyrrolidone, a terpene, and combinations of any of the foregoing.

221. The method of claim 211, wherein the gelling agent comprises polyacrylic acid.

222. The method of claim 211, wherein the composition further comprises an alcohol selected from the group consisting of: ethanol and isopropyl.

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223. The method of claim 211, wherein the composition further comprises from about 1% to about 5% (w/w) 0.1 N sodium hydroxide.

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234. A method for treating erectile dysfunction in a male subject, comprising administering in combination:

a) a hydroalcoholic topical gel composition to selected skin of a male subject, wherein the composition comprises about 0.1% to about 10% (w/w) testosterone, about 0.1% to about 5% (w/w) of at least one penetration enhancer, and about 0.1% to about 5% (w/w) of at least one gelling agent, and

b) a pharmaceutical useful for treating erectile dysfunction in the subject, wherein the composition and pharmaceutical are administered in amounts sufficient to treat the erectile dysfunction,

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wherein the method is more effective in treating erectile dysfunction than a method comprising the administration of either the pharmaceutical or the composition alone.

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235. The method of claim 234, wherein the pharmaceutical comprises at least one of: sildenafil, pentoxifylline, yohimbine, apomorphine, alprostadil, papaverine, IC-351 (tadalafil) and phentolamine, or a combination, salt, or enantiomer thereof.

240. The method of claim 234, wherein the composition comprises about 1.0% w/w of testosterone. ✓

241. The method of claim 234, wherein the combination has a synergistic effect in treating erectile dysfunction. ✓ 112-158

242. The method of claim 234, wherein the penetration enhancer is selected from the group consisting of: isostearic acid, octanoic acid, oleic acid, oleyl alcohol, lauryl alcohol, ethyl oleate, isopropyl myristate, butyl stearate, methyl laurate, diisopropyl adipate, glyceryl monolaurate, tetrahydrofurfuryl alcohol polyethylene glycol ether, polyethylene glycol, propylene glycol, 2-(2-ethoxyethoxy)ethanol, diethylene glycol monomethyl ether, alkylaryl ethers of polyethylene oxide, polyethylene oxide monomethyl ethers, polyethylene oxide dimethyl ethers, dimethyl sulfoxide, glycerol, ethyl acetate, acetoacetic ester, N-alkylpyrrolidone, a terpene, and combinations of any of the foregoing.

245. The method of claim 234, wherein the composition further comprises an alcohol selected from the group consisting of: ethanol and isopropyl.

246. The method of claim 234, wherein the pharmaceutical comprises sildenafil in an amount of about 25 mg to about 100 mg.

247. The method of claim 234, wherein the composition further comprises about 1% to about 5% 0.1 N sodium hydroxide.

248. The method of claim 234, wherein the pharmaceutical comprises apomorphine in an amount of about 1 mg to about 5 mg.

251. The method of claim 234, wherein the pharmaceutical comprises IC-351 (tadalafil) in an amount of about 5 mg to about 30 mg.

359. A method for treating erectile dysfunction in a male subject, comprising administering in combination:

a) a hydroalcoholic topical gel composition to selected skin of a male subject, wherein the composition comprises about 0.1% to about 10% (w/w) testosterone; about 0.1% to about 5% (w/w) of at least one penetration enhancer selected from the group consisting of: isostearic acid, octanoic acid, oleic acid, oleyl alcohol, lauryl alcohol, ethyl oleate, isopropyl myristate, butyl stearate, methyl laurate, diisopropyl adipate, glyceryl monolaurate, tetrahydrofurfuryl alcohol polyethylene glycol ether, polyethylene glycol, propylene glycol, 2-(2-ethoxyethoxy)ethanol, diethylene glycol monomethyl ether, alkylaryl ethers of polyethylene oxide, polyethylene oxide monomethyl ethers, polyethylene oxide dimethyl ethers, dimethyl sulfoxide, glycerol, ethyl acetate, acetoacetic ester, N-alkylpyrrolidone, a terpene, and combinations of any of the foregoing; and about 0.1% to about 5% (w/w) of at least one gelling agent, and

b) a pharmaceutical selected from the group consisting of: sildenafil, pentoxifylline, yohimbine, apomorphine, alprostadil, papaverine, IC-351 (tadalafil) and phentolamine, or a combination, salt, or enantiomer thereof; wherein the composition and pharmaceutical are administered in amounts sufficient to treat the erectile dysfunction, and wherein the method is more effective in treating erectile dysfunction than a method comprising the administration of either the pharmaceutical or the composition alone.

361. The method of claim 359, wherein the composition comprises about 1.0 % w/w of testosterone.

365. The method of claim 359, wherein the composition further comprises an alcohol selected from the group consisting of: ethanol and isopropyl.

366. The method of claim 359, wherein the combination has a synergistic effect in treating erectile dysfunction.

367. The method of claim 359, wherein the composition further comprises from about 1% to about 5% (w/w) 0.1 N sodium hydroxide.

373. The method of claim 359, wherein the pharmaceutical comprises sildenafil in an amount of about 25 mg to about 100 mg.

375. The method of claim 359, wherein the pharmaceutical comprises apomorphine in an amount of about 1 mg to about 5 mg.

376. The method of claim 359, wherein the pharmaceutical comprises IC-351 (tadalafil) in an amount of about 5 mg to about 30 mg.